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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re:	)	Master File No.
SILICONE GEL BREAST IMPLANTS	)	CV 92-P-10000-S
PRODUCTS LIABILITY LITIGATION	)	
(MDL 926)	)	This document applies to all cases

Memorandum of Opinion
(Granting Motion by General Electric Company for Reconsideration and Summary Judgment)

Under submission after extensive discovery, briefing, and oral argument is a motion by defendant General Electric Company ("GE") requesting reconsideration of this Court's March 20, 1996, opinion and order, which had denied GE's motion for summary judgment. GE seeks summary judgment in all breast implant cases currently pending in, or later filed in, removed to, or transferred to this court. It contends that, contrary to the earlier order, it is not liable for alleged injuries to breast-implant recipients inasmuch as it was merely a bulk supplier of raw materials to sophisticated purchasers and had no duty to provide warnings to implant manufacturers or to breast-implant recipients or their physicians. For the reasons stated below, GE's motion is due to be granted.[1/]

I. STANDARD OF REVIEW

The March 1996 order, denying GE summary judgment at that time, was, both by virtue of the Federal Rules of Civil Procedure and by express language in the order itself, an interlocutory, not a final, ruling. It did not become the "law of the case," nor did it bar (or change the applicable legal standards for deciding) a later, or renewed, motion for summary judgment by the same party. *Dictograph Prod. Co. v. Sonotone Corp.*, 230 F.2d 131 (2d Cir. 1956). A party should not, of course, harass adversaries or the court by filing repetitive Rule 56 motions with no reasonable expectation of success. A renewed motion, however, may sometimes be appropriate, whether because of changes or developments in the applicable law, because of additional evidentiary matters, or because of factual errors in the original decision—or, on occasion, simply

1. GE's motion has been considered in conjunction with a motion by Union Carbide Corporation ("Union Carbide") for partial summary judgment. Like GE, Union Carbide asserts the bulk supplier/sophisticated purchaser and raw materials supplier doctrines to absolve itself from potential tort liability.

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to provide the judge with an opportunity to change his or her mind.

GE has been named as a defendant in thousands of cases pending in this court.[2] It is important—certainly to GE but also to plaintiffs, albeit to a lesser degree since they routinely have also sued other defendants—that this court correctly decide whether GE is entitled to summary judgment. Therefore, although GE has described its motion as one for reconsideration and although plaintiffs have argued for a narrow standard of review, the court has considered GE's request for summary judgment afresh, under the same legal standards that apply to all Rule 56 motions. The court does, however, treat as before it the evidentiary materials and briefs previously submitted by the parties in connection with the original motion, as well as those submitted in connection with the present motion. Likewise, Parts I, II, and III of the March 1996 opinion should be viewed as part of the court's decision except where inconsistent with or modified by this opinion.[3]

Most of the basic facts pertinent to GE's request for summary judgment were recited in Part III of the March 1996 opinion,[4] and they will not be repeated in any detail in this opinion except where some modification or clarification is needed.[5] Similarly, the general principles governing summary judgment motions and choice of law considerations, as contained in Parts I and II of the March 1996 opinion, need not be repeated here. As stated in that opinion, this court, with respect to cases transferred to it under 28 U.S.C. § 1407,[6] is bound to apply the substantive laws of numerous transferor courts and cannot grant summary judgment in all cases, as requested by GE, unless there would be no genuine dispute as to a material fact under any applicable state law.

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2. So far as can be determined, no court has permitted a claim against GE to proceed to trial, and, although GE has not paid any amounts in settlement, many plaintiffs have already dismissed GE as a defendant.

3. For a further explication of the court's views regarding the current state of the law, see also the opinion accompanying Order No. 37, which grants Union Carbide's summary judgment and is being filed contemporaneously with this order.

4. For purposes of summary judgment, the court treats as "fact" the evidence viewed in the light most favorable to the plaintiffs.

5. For example, the March 1996 opinion, after referring to a 1958 study involving silicone oil in rats, indicated that "GE had concerns about the dangerous condition of breast implants as early as 1958." GE correctly points out that this statement was in error since breast implants were not invented until the early 1960s. The opinion should have said that, long before GE began selling silicone compounds for use in breast implants, it had known of possible biological effects when silicone oils were ingested by rats.

6. At the present time, this court has received through the Judicial Panel on Multidistrict Litigation cases from 93 of the 94 federal district courts. GE has been named as a defendant in cases transferred from many, though not all, of these courts.

II. ANALYSIS

GE contends, as it did in its original motion for summary judgment, that it cannot be held liable for alleged injuries to breast-implant recipients inasmuch as it was merely a bulk supplier of generally safe raw materials to sophisticated purchasers, who substantially changed these materials in the manufacturing process, and, accordingly, it had no duty to provide warnings to implant manufacturers or to breast-implant recipients or their physicians. In its prior opinion, this court was not persuaded that GE would prevail in all states under these raw materials supplier and bulk sale/sophisticated purchaser doctrines—a decision that perhaps was unduly influenced by the fact that GE's position was not as compelling as had been Scotfoam's in an earlier motion for summary judgment.[7] The court opined that under the substantive law of at least some states a reasonable trier of fact could find that GE was liable to implant recipients under the principles of § 402A or § 388 of the Restatement (Second) of Torts (1965). However, upon reconsideration—particularly in the light of further developments in the law, developments that have not so much changed the law as made it more certain—the court concludes that GE is entitled to summary judgment.

Claims under state law analogs of § 402A and § 388, as well as claims based on other strict liability or common law negligence theories, are, as GE correctly contends, subject to what has been characterized as the "raw material supplier defense" or the "bulk sales/sophisticated purchaser rule." These two doctrines, though conceptually distinct, overlap and tend to merge, as is recognized in Section 5 of the Proposed Final Draft of the Restatement of the Law of Torts: Products Liability (Third). What divergence exists between the various courts, apart from the labels, is not whether to apply the doctrines, but the significance of various factors—such as the extent to which the raw materials are themselves inherently dangerous, the extent to which the materials are changed before integration into the end-product, and the extent to which the supplier was involved in designing the end-product.

Included as Comment *p* to § 402A of Restatement (Second) of Torts (1965) was the following:

> The manufacturer of pigiron, which is capable of a wide variety of uses, is not so likely to be held to strict liability when it turns out to be unsuitable for the child's tricycle into which it is finally made by

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7. *In re Silicone Gel Breast Implants Prod. Liab. Lit. (MDL 926)*, 887 F.Supp. 1463 (N.D.Ala. 1995).

> a remote buyer. The question is essentially one of whether the responsibility for discovery and prevention of the dangerous defect is shifted to the intermediate party who is to make the changes.

Though premised on the fundamental notion that responsibility should generally be placed on the manufacturer that selects a material for incorporation into its own product, this comment recognized in the then-existing law two subsidiary principles that, on occasion, have been important in deciding whether to apply the doctrine; namely, the extent to which the materials supplied have safe uses in other applications and the extent to which those materials undergo changes before incorporation into the finished product distributed to the ultimate consumer.

Over the years, the raw material/bulk supplier doctrines have been expressly adopted by a large number of jurisdictions. *See In re Silicone Gel Breast Implants Prod. Liab. Lit.*, 887 F. Supp. 1463, 1467 (N.D. Ala. 1995); *In re TMJ Implants Prod. Liab. Lit.*, 872 F. Supp. 1019, 1029 (D.Minn. 1995) (quoting American Law of Products Liability 3d § 5.23 (Matthew J. Canavan, ed. 1994)). These opinions cite decisions applying the doctrines under the law of Alabama, California, Connecticut, Florida, Georgia, Hawaii, Illinois, Kansas, Louisiana, Michigan, Minnesota, Missouri, New Jersey, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin. Moreover, in the DuPont cases involving temporomandibular jaw (TMJ) implants, each federal circuit confronted with the issue has likewise applied the doctrines. *See Kealoha v. E.I. DuPont de Nemours & Co.*, 82 F.3d 894 (9th Cir. 1996) (applying Hawaii law); *LaMontagne v. E.I. DuPont de Nemours & Co.*, 41 F.3d 846 (2d. Cir. 1994) (applying Connecticut law); *Apperson v. E.I. DuPont de Nemours & Co.*, 41 F.3d 1103 (7th Cir. 1994) (applying Illinois law); *Klem v. E.I. DuPont de Nemours & Co.*, 19 F.3d 997 (5th Cir. 1994) (applying Louisiana law). Indeed, the doctrine has apparently been adopted in all states in which the question has been presented, and this court must conclude that—albeit with some variations regarding the burden of proof, the effect of inherent dangers of the raw materials, or the extent of changes made in the raw materials—the doctrines must be considered a part of the products liability law of each jurisdiction.

Sometimes a supplier has been sued when it was unaware that its product had been subsequently

incorporated by intermediate manufacturers into other products.[8] However, given the underlying rationale—that the supplier of nondefective and reasonably safe products should not be responsible for determining the safety of such products when transformed by another company into other goods—the supplier is not liable merely because the end use is foreseeable or even known. As the district court in *Kealoha* stated:

> [t]he alleged foreseeability of the risk of the finished product is irrelevant to determining the liability of the component part manufacturer because imposing such a duty would force the supplier to retain an expert in every finished product manufacturer's line of business and second-guess the finished product manufacturer whenever any of its employees received any information about any potential problems.

Kealoha v. E.I. DuPont de Nemours & Co., 844 F. Supp 590, 594 (D. Haw. 1994) (citing *Childress v. Gresen Mfg. Co.*, 888 F.2d 45, 49 (6th Cir. 1989)), *aff'd*, 82 F.3d 894 (9th Cir. 1996).

The expected development of the bulk/raw materials supplier doctrine, as presaged in the 1965 Restatement (Second), has been recognized in the Proposed Final Draft of the Restatement of the Law of Torts: Products Liability (Third), which was approved at the May 20, 1997, meeting of the American Law Institute. Section 5, entitled "Liability of Commercial Seller or Distributor of Product Components for Harm Caused by Products Into Which Components Are Integrated," addresses the liability of component sellers whose products are incorporated into another's final product.

Comment *b* to this section concisely explains the basis of the "sophisticated buyer" doctrine:

> [W]hen a sophisticated buyer integrates a component into another product, the component seller owes no duty to warn either the immediate buyer or ultimate consumers of dangers arising because the component is unsuited for the special purpose to which the buyer puts it. To impose a duty to warn in such a circumstances would require that component sellers monitor the development of products and systems into which their components are to be integrated.

And Comment *c* addresses the reasons for absolving raw materials suppliers from liability:

> [R]aw materials sellers are not subject to liability for harm caused by defective design of the end-product. To impose a duty to warn would require the seller to develop expertise regarding a multitude of different end-products and to investigate the actual use of raw materials by manufacturers over whom the supplier has no control. Courts uniformly refuse to impose such an onerous duty to warn.
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> Justification for absolving a supplier from liability to ultimate users of the end-product is strongest if

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8. In an earlier decision granting summary judgment in favor of another supplier, this court noted that Scotfoam was unaware its products were being incorporated into implants. *In re Silicone Gel Breast Implants Prod. Liab. Lit. (MDL 926)*, 887 F. Supp. 1463 (N.D. Ala. 1995).

the elements of both the sophisticated purchaser and the raw materials supplier doctrines are present; namely, when a supplier sells to a knowledgeable manufacturer raw materials in bulk, which are not themselves inherently dangerous and which are substantially changed during the manufacturing process before resale to consumers, and when the supplier has little or no role in the design of the end product. Each of these elements supports GE's motion for summary judgment.

First, it is clear that the silicone products sold in bulk by GE to implant manufacturers had many safe uses and were not themselves inherently defective or unreasonably dangerous. Even those compounds developed by GE at the request of implant manufacturers—RTV-6191, CRTV-6193, CRTV-6195 and RTV-7100—were sold to various other companies, including Aerospace Corporation, Goodyear, International Paper, IBM, and Martin Marietta, by whom the compounds were safely incorporated into various products, such as electronic semi-conductors and orthopedic bed pads. These silicone compounds became potentially harmful, if at all, only in particular applications—here, according to plaintiffs, when incorporated into breast implants by the various manufacturers using their own designs and manufacturing processes.

Second, it is clear that the three implant manufacturers to which GE sold its products—namely, Medical Engineering Corporation ("MEC"), Heyer-Schulte Corporation ("Heyer-Schulte"), and McGhan Medical Corporation ("McGhan Medical")—were "sophisticated" buyers. Each was a leading manufacturer of breast implants, under an independent duty to provide appropriate warnings to its customers and subject to certain FDA regulations. Competing with one another and with Dow Corning and other companies that came into the industry, each was regularly exploring and making changes in the design and manufacture of its implants. Each was aware of—and was in a position to evaluate (and, to varying degrees, did test and evaluate)—the potential risks of its particular products and their constituent elements. *See Kealoha v. E.I. Du Pont de Nemours & Co.*, 82 F.3d 894, 901 (9th Cir. 1996). To recount briefly the evidence—

> MEC: Wilfred Lynch, a former president of MEC, testified that he knew about silicone gel bleed from the first time he was involved in marketing breast implants. According to Lynch, MEC ran tests to determine the amount of gel bleed occurring with various molecular weights of gel material, the tests confirming that silicone implants did bleed low-molecular-weight silicone. He also testified that manufacturers such as MEC frequently consulted with plastic surgeons about problems related to implants, including capsular contracture, a condition Lynch believed was related to the phenomenon of gel bleed.

Heyer-Schulte: Don McGhan and Richard Compton, who were employed by Heyer-Schulte as executives in the early 1970s, had previously worked for Dow Corning (the developer and major producer of silicone-gel implants and components), and, between the two of them, brought to Heyer-Schulte considerable experience in the design and manufacture of implants. As early as April 1974, Compton, in an internal Heyer-Schulte memorandum, advised that the "oily" build-up on a patch of an implant was probably due to permeation of gel through the intact pouch.

McGhan Medical: This company was founded by, among others, Don McGhan and Richard Compton, who, as previously indicated, had worked for Dow Corning and later for Heyer-Schulte. McGhan and Compton had many years of experience in the implant business, and were very knowledgeable about the selection of materials and the manufacturing processes in producing breast implants. McGhan Medical touted this expertise in promoting the various implants that it designed and produced.

Compared to GE, each of these end-product manufacturers was in a far superior position to determine the risks and provide appropriate warnings regarding its breast implants. Indeed, each was actively engaged in providing such information—albeit challenged by plaintiffs as to accuracy and completeness—to its physician-customers and in receiving and responding to product questions and complaints from those physicians.

Nor should one ignore the virtual impossibility and minimal utility of requiring GE to provide to ultimate consumers—the physicians and the implant recipients—warnings concerning its knowledge of possible hazards of silicone products.[9/] GE had done no testing to determine whether the substances were safe for use in implants. It did not promote its silicone materials as safe for use in implants, and GE's product data sheets cautioned that the users were responsible for determining the safety, compatibility, and approval necessary for use in any medical application. Although GE was privy to some information not possessed by the manufacturers regarding environmental and biological effects of silicones,[10/] it can hardly be said that such information, if known by the manufacturers, would have resulted in any changes in their design, production, or distribution of implants. The minimal information that GE had about potential problems with

9. The March 1996 opinion of this court was in error to the extent it implied that, without undue burden, GE might have itself provided appropriate warning to physicians and potential implant recipients.

10. Long after GE's motion was taken under submission, plaintiffs requested that they be allowed to file as additional evidence (primarily in support of a claim based on post-sale duty to warn) some 30,000 documents, listed in a 452-page index. These materials were obtained by plaintiffs from the Silicones Environment Health and Safety Council ("SEHSC"), a trade association representing organosilicone manufacturers in North America, one of whose members was GE. This request is denied. Based on the index, virtually all appear to be animal studies that were conducted by some other silicone producer and later submitted to the EPA. Again based on the index, none of the items appears to have been generated by or on behalf of GE or to have involved a GE product, and less than a dozen appear to have been sent to GE. None appears to have involved a study of implants.

implants—such as complaints about gel-bleed, granulomas, and migration—was, of course, known by the implant manufacturers.

Third, it is clear that the raw materials sold by GE did undergo "substantial changes" in the process of being incorporated by the three manufacturers into their finished implants. This court's conclusions to the contrary in its March 1996 opinion were incorrect. The "dispute" generated by plaintiffs as to the extent of such changes should not have been treated by the court as a "genuine dispute" under Rule 56. Although there were variations in the manufacturing processes employed by the three companies, the procedures were generally as follows:

> GE's silicone materials were shipped to the manufacturers in bulk in fifty-five-gallon drums and five-gallon pails. The compounds then underwent a multistep process by the manufacturers that first included mixing the shell materials with a solvent selected by the implant manufacturer, mixing the shell materials together,[11] and dipping a "mandrel" in the shell mixture to achieve the desired thickness of the shells. The shells were then baked to cause "curing" and "cross-linking" to occur, and resulting in a chemical change in the materials. Next, the manufacturer cut holes in the shells and peeled the shells off the mandrels by hand and patched the holes in the shells. The manufacturer separately mixed the gel compounds together and injected the gel mixture into the finished shells, patched the injection holes, and baked the assembled implants. Then—after perhaps adding some accessories such as "suture loops" and "fixation patches"—the manufacturer individually sterilized and packaged the implants.

What physicians and implant recipients ultimately obtained from the implant manufacturers was undeniably a product quite different from the materials that GE sold to the manufacturers.

The fourth and final element—involving the extent to which GE participated in the integration of its materials into the design of the end-products—is more problematic here than when it was addressed respecting Union Carbide's motion for summary judgment. The issue is not whether GE was aware of the use to be put by implant manufacturers of its materials—clearly it knew this—though, as indicated earlier in this opinion, such awareness by itself is irrelevant to imposition of liability. Rather, the question is whether GE's involvement with implant manufacturers in developing silicone compounds for their applications or in responding to manufacturing problems might be viewed as creating liability under Section 5(b) of the Proposed Final Draft of Restatement of the Law Torts: Products Liability (Third)—the liability of the supplier of a component part if it "*substantially participates* in the design of the component into the design of the

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11. Unlike Union Carbide, GE did provide to implant manufacturers recommendations regarding ratios for mixing materials. The manufacturers, however, made their own independent decisions as to the most appropriate ratios.

product" and "the integration of the component causes the product to be defective." (Emphasis added.)

Some of GE's silicone compounds were developed by it to satisfy product requirements specified by MEC. Also, GE provided recommendations regarding ratios for mixing materials—though the manufacturers made their own independent decisions as to what mixing ratios they used. And, from time to time, GE provided technical assistance to implant producers (as it did for its other customers) in solving manufacturing problems. As recited in the March 1996 opinion, MEC's founder conferred with a chemist at GE about the clarity of implant shells and why the shells tended to leak gel, and on one occasion Heyer-Schulte obtained GE's help in solving a manufacturing problem involving the uneven distribution of CRTV-7100, which was causing ripples on implant shells.

One of the comments to Section 5, together with an illustration, is quite helpful in assessing whether GE's activities should be viewed as substantial participation or as being a cause of the claimed harm.[12/] Comment *e* reads in part :

> A component seller who simply designs a component to the buyer's specifications, and does not substantially participate in the integration of the component into the design of the product, is not liable within the meaning of Subsection (b). Nor does providing mechanical or technical services or advice in the selection or integration of the component into a product over whose overall design, testing, or labelling the component supplier does not exercise control constitute substantial participation which would subject the component supplier to liability.

According to the accompanying illustration:

> 6. ABC Chemical Co. sells plastic resins in bulk. XYZ Hot Water Heater Manufacturing Co. informs ABC that XYZ wishes to purchase resin for use in making it hot water heaters and specifies resins that can withstand heat up to 212° Fahrenheit. ABC recommends that XYZ use a certain type of resin which, in ABC's testing under specified laboratory conditions, including thickness of one quarter inch or more, was shown to be capable of withstanding temperatures in excess of 212° Fahrenheit. ABC explains these conditions to XYZ. ABC also provides XYZ with technical support and general processing advice. XYZ purchases the recommended resin from ABC and decides upon design and processing parameters, molds the resin into a plastic part, and combines the part with other materials and parts to produce hot water heaters. XYZ tests its hot water heaters for safety and durability and formulates instructions and warnings to accompany them. An XYZ hot water heater subsequently fails because the plastic walls specified by its design, one-eighth inch thick, were too thin to withstand the stress imposed by its normal operating temperatures, resulting in injury to a homeowner. ABC is not liable to the homeowner. The resin sold by ABC was not in itself defective. ABC did not substantially participate in the design, manufacture or assembly of the hot water heater.

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12. The quoted materials include language from the Reporters' Amendment No. 9, which was adopted by the ALI at the May 1997 meeting.

Here, as in Illustration 6, the assistance provided by GE must be viewed as technical services and advice. It does not constitute such substantial participation in the design of the integrated products as would subject GE to potential liability if those products were shown to be defective.

To summarize, the court concludes that GE has established that it is shielded from liability under the raw materials supplier and bulk sales/sophisticated purchaser doctrines. To the extent that the plaintiffs have asserted other causes of action against GE, whether under other sections of the Restatement such as § 302B, § 324A, and § 389, or under statutes and common-law doctrines—*e.g.*, breach of warranty, fraudulent misrepresentation, post-sale duty to warn—these claims either are similarly precluded by the raw materials/bulk supplier/sophisticated purchaser doctrines or are factually unsupported. The March 1996 order was in error in denying GE summary judgment. A desire for consistency cannot justify a perpetuation of error.

III. CONCLUSION

The Court hereby GRANTS GE's motion for reconsideration and summary judgment. By separate order, summary judgment will be entered in favor of GE. All claims against GE will be severed under Fed. R. Civ. P. 42 from other issues and claims remaining in this litigation, and the order dismissing these claims will be made final under Fed. R. Civ. P. 54(b). It is appropriate and desirable to make this determination under Rule 54(b) because this will, if not reversed on appeal, result in the dismissal of GE in hundreds, if not thousands, of cases and will result in shorter and less confusing trials of claims against the remaining defendants in those cases.

This the 22nd day of August, 1997.

Sam C Pointer

Chief Judge Sam C. Pointer, Jr.